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(71) Applicant (for all designated States except US):  
**GRAMPIAN UNIVERSITY HOSPITALS NHS TRUST** [GB/GB]; Foresterhill House, Ashgrove Road West, Aberdeen AB25 2ZB (GB).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **JOHNSTONE, Alan, John** [GB/GB]; The Elms, 7 North Deeside Road, Bieldside, Aberdeen AB15 9AD (GB).

(74) Agent: **MURGITROYD & COMPANY**; 165-169 Scotland Street, Glasgow G5 8PL (GB).

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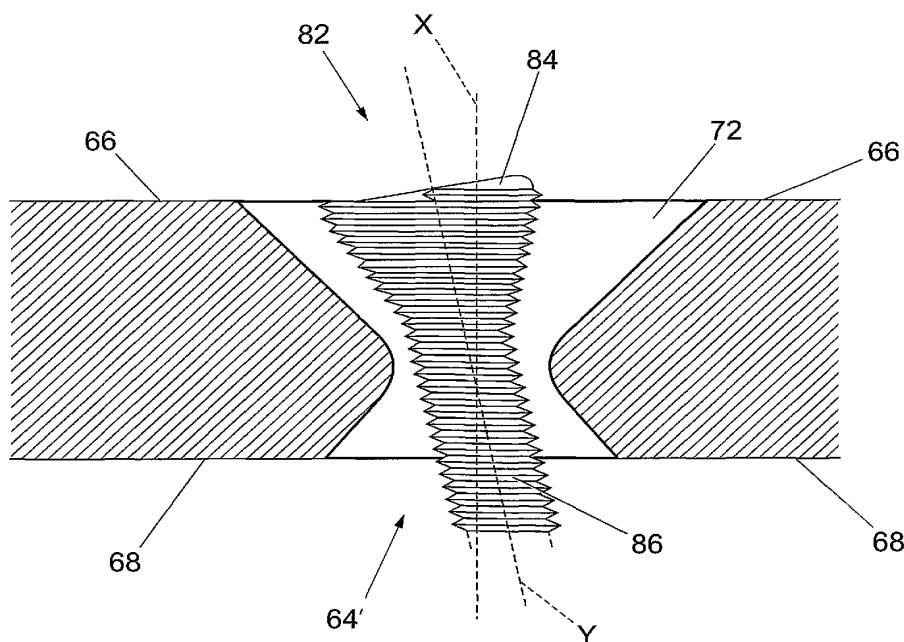
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(54) Title: APPARATUS



(57) Abstract: A bone fixture apparatus such as plate or an intramedullary nail is disclosed, having a plug or other form of insert that engages screws passing through the nail or plate etc. The provision of the pliable insert allows the screw to be driven through the plate etc at a number of different angles. The application also concerns a pliable insert suitable for use with the plate or nail.

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*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

1     "Apparatus"

2

3     This invention relates to apparatus for use in  
4     supporting a fractured bone.

5

6     It is known to support fractures in bones by rigid  
7     bone fixture implants, common examples of which are  
8     bone plates (commonly known as interlocking plates)  
9     and intra-medullary (IM) nails.

10

11     IM nails are inserted into the medullary canal of  
12     the long bone, and are held in place by screws or  
13     other bone fasteners such as bolts or pins that are  
14     driven laterally through the bone, typically at each  
15     end of the nail. The screws etc also pass through  
16     pre-drilled holes in the nail, thereby reducing or  
17     preventing movement of the nail while the fracture  
18     is healing. Holes must be bored through the bone in  
19     order to insert the screws, and these must be  
20     aligned with the pre-drilled holes in the ends of  
21     the nail.

22

1 In order to drill the holes accurately through the  
2 bone, a jig is commonly employed. The jig is  
3 attached to the protruding end of the nail after  
4 insertion of the nail into the medullary canal, and  
5 typically extends parallel to the nail. The jig has  
6 pre-drilled holes that align with the holes in the  
7 nail when the jig and the nail are properly  
8 attached.

9  
10 Interlocking bone plates are normally attached to  
11 the exterior surface of bones using similar bone  
12 fasteners such as bolts or screws. Like the IM  
13 nail, the plate is arranged to span fractures and  
14 the bone fasteners penetrate solid bone on opposing  
15 sides of the fracture(s).

16  
17 According to the present invention there is provided  
18 a bone fixture apparatus having a pliable material  
19 for engaging a fixing device.

20  
21 The bone fixture apparatus can be attached to the  
22 outer or the inner surface of the bone. Typically,  
23 the bone fixture apparatus comprises an intra-  
24 medullary nail. Alternatively, the bone fixture  
25 apparatus comprises a bone plate (internal or  
26 external). Alternatively, the bone fixture  
27 apparatus comprises a fracture brace.

28  
29 Typically, the pliable material is capable of  
30 plastic and/or elastic deformation, and can  
31 typically be a coating or insert. The pliable  
32 material is typically softer than the material of

1 the bone fixture apparatus, and has a lower Young's  
2 modulus. The pliable material is preferably soft  
3 enough to drill, mill or cut peroperatively,  
4 typically under the influence of materials that are  
5 harder than the pliable material. Typically such  
6 harder materials are used for the fixing device  
7 which is driven into the pliable material.

8  
9 Optionally, the pliable material is a metal or a  
10 polymer. In certain embodiments the pliable  
11 material can be biodegradable. Biodegradable  
12 variants are useful as the plate or nail typically  
13 needs to be firmly attached to the bone without  
14 allowing any movement only in the initial phase of  
15 the fracture, so that it can take the loading  
16 normally applied to the fractured area of bone  
17 arising from everyday use. After the fracture has  
18 healed, the implant is redundant and no longer needs  
19 to bear any load. In some cases, the implant can be  
20 left in place permanently, but in other cases, the  
21 implant can be removed from the bone, and  
22 biodegradable inserts of the pliable material can  
23 assist in such removal, as by the time the bone has  
24 healed, the pliable material will have been eroded,  
25 and the fixings can be more easily removed.

26

27 Biodegradable versions of the insert also lend  
28 themselves very well to use with bone plates having  
29 dynamization slots, as the screw can be driven  
30 through the dynamization slot filled with the  
31 pliable insert, and the degradation of the insert  
32 over the succeeding weeks or months will then free

1 the screw to move axially in the slot once the  
2 initial healing has progressed to a suitable phase  
3 where this movement is desirable, but retaining a  
4 secure fixing of the screw, plate and bone when this  
5 is necessary in the initial phase before healing of  
6 the bone fracture.

7  
8 The pliable material can be a non-metallic material  
9 such as plastics material or an expanded carbon  
10 complex. A further possibility is that the pliable  
11 material is a naturally occurring (and preferably  
12 bioabsorbable) material such as a collagen or  
13 polypeptide construct.

14  
15 The apparatus may have a hole to receive the fixing  
16 device, and the pliable material may preferably be  
17 located at or in the hole. Preferably, the pliable  
18 material is positioned e.g. bonded on a surface  
19 (typically the internal surfaces of an aperture or  
20 bore) of at least a part of the bone fixture  
21 apparatus. Preferably, some pliable material is  
22 disposed in the region(s) of the bone fixture  
23 apparatus around or within the hole(s). In some  
24 embodiments in the form of hollow nails etc, the  
25 pliable material can be inserted into a central  
26 canal of the nail.

27  
28 In some embodiments, the pliable material is  
29 settable so that it changes phase (e.g. from paste,  
30 gel or liquid to a solid) on the application of  
31 pressure or heat, when exposed to a chemical

1 catalyst, or after an interval of time. Optionally,  
2 the settable material is a glue or a paste.

3  
4 The pliable material is optionally self-expanding.  
5 Optionally, the pliable material changes phase, e.g.  
6 from liquid to solid when it expands.

7  
8 Optionally, the bone fixture apparatus has  
9 predrilled holes to receive fixings. The holes can  
10 be on different planes, and can be lateral holes or  
11 in other planes. The holes can be filled or lined  
12 with pliable material. Optionally, screws or other  
13 bone fixings are inserted into the pliable material  
14 to form holes through the pliable material. In such  
15 cases the bone fixture apparatus can have a window  
16 through which the pliable material is exposed to the  
17 fixing, and through which the screw etc can be  
18 inserted. In certain cases the pliable material can  
19 have a pilot hole pre-drilled therein to receive the  
20 bone fixing.

21  
22 Preferably, the fixing device is a screw or a bolt.  
23 Threaded fixings are preferred, but non-threaded  
24 fixings such as pins etc can be used. Preferably,  
25 the fixing device is longer than the diameter of the  
26 apparatus.

27  
28 In some nails formed as a rolled tube, each hole has  
29 a circumferentially opposite hole. Each hole (or  
30 pair of opposite holes) can typically receive the  
31 fixing device. Potentially, the pair of opposite  
32 holes could form the ends of a generally cylindrical

1 passage through a solid nail. The entire passage  
2 could be filled with pliable material, or  
3 alternatively the walls of the passage could be at  
4 least partially lined with pliable material. In  
5 some embodiments the pliable material can comprise  
6 at least one ring (preferably two rings) of e.g.  
7 plastics material such as Nylon(TM) on the inner  
8 diameter of (or within) at least one of the holes  
9 (preferably each end of each hole has a respective  
10 ring).

11  
12 Optionally, the pliable material extends down the  
13 full length of cannulated nails, although it is only  
14 necessary for the pliable material to be located  
15 where the fixing devices engage the bone fixture  
16 apparatus; thus the pliable material and/or the  
17 holes to engage the bone fixings could be anywhere  
18 on the apparatus.

19  
20 Optionally, the holes have parallel sides, but in  
21 certain embodiments, the sides of the holes are  
22 tapered. Bi-directionally tapered embodiments,  
23 where the sides of the holes taper inwardly from  
24 both the upper and lower surfaces of the bone fixing  
25 apparatus to an apex, can be advantageous, as the  
26 narrower width of the hole at the apex can serve to  
27 hold the pliable material in position, without the  
28 need for an adhesive. The apex of the hole is  
29 typically located just below the centre point of the  
30 hole axis. The embodiments having bi-directional  
31 tapering are typically used with a solid insert of



1     pliable material which fills, or nearly fills the  
2     hole.

3  
4     Optionally, the pliable material is in the form of  
5     an insert which has a compressible portion. This  
6     kind of insert is especially useful for use with  
7     holes having a narrow portion. The compressible  
8     portion can be compressed to fit through the narrow  
9     portion of the hole. The compressible portion may  
10    have legs divided by elongate slits. The slits are  
11    typically wedge-shaped, and allow for the legs to be  
12    pushed together to reduce the diameter of the  
13    compressible portion. For example, before  
14    compression, the legs may form part of a frusto-  
15    conical portion of the insert; thus the legs have a  
16    partially radial extent. On compression, the legs  
17    can be squeezed into a cylindrical shape to fit  
18    through the narrow portion of the hole. It is  
19    useful if the compressible portion is formed from a  
20    resilient material, so that when the legs have  
21    passed through the narrow portion of the hole, they  
22    extend radially outwards again to hold the insert in  
23    the hole.

24  
25    Other embodiments of bone fixing apparatus have  
26    tapered frusto-conical holes. These may be used  
27    with inserts which fill the holes, or alternatively,  
28    the hole walls may be lined with the pliable  
29    material.

30  
31    The holes in the bone fixing apparatus may be screw-  
32    threaded and the pliable material may be in the form

1 of an insert having corresponding threads;  
2 alternatively, threads may be formed in the insert  
3 on screwing the insert into the threaded holes.

4

5 Optionally, the nail can be hollow and the entire  
6 cross-section of the nail is filled with the pliable  
7 material, at least in the areas where the screws  
8 will engage the nail, e.g. at the ends.

9 Alternatively, the bone fixture apparatus can be  
10 solid and the pliable material can comprise a hollow  
11 sleeve or ring(s), or a solid plug inside a passage  
12 through the bone fixture apparatus adapted to  
13 receive the fixing screws. Another possibility is  
14 that the pliable material lines the inside surface  
15 of a hollow bone fixture apparatus.

16

17 According to a further aspect of the present  
18 invention, there is provided a method of supporting  
19 a fractured bone, the method comprising the steps  
20 of: attaching a bone fixture apparatus to the bone  
21 and engaging at least one fixing device with the  
22 bone, wherein the bone fixture apparatus is provided  
23 with a pliable material and the fixing device is  
24 engaged with the pliable material.

25

26 The bone fixture apparatus may comprise an intra-  
27 medullary nail, and the method optionally includes  
28 the step of inserting the intra-medullary nail into  
29 the medullary cavity of the bone. Alternatively,  
30 the bone fixture apparatus may comprise a bone  
31 plate.

32

1 Preferably, the apparatus spans one or more  
2 fractures in the bone, and the screws are driven  
3 into the bone fixture apparatus on opposing sides of  
4 the fracture(s).

5

6 The pliable material is typically attached to a part  
7 of the bone fixture apparatus.

8

9 The fixing device may optionally be inserted through  
10 at least one hole in the bone fixture apparatus; the  
11 hole is typically at least lined and optionally  
12 filled with pliable material. The pliable material  
13 may be inserted into the hole either before or after  
14 the bone fixture apparatus is attached to the bone.

15

16 A simple option is to fill the holes in the bone  
17 fixture apparatus with pliable material. A simple  
18 ring of plastic material around the inside of each  
19 hole would be sufficient, and in such cases the  
20 inner diameter of the ring is preferably less than  
21 the diameter of the shank of the screw. Another  
22 possibility is to insert one or more sleeves or  
23 cylinders of pliable material to span the gap(s)  
24 between holes in opposite sides of a hollow bone  
25 fixture apparatus and is supported by the holes.

26

27 Typically, the pliable material acts to minimize  
28 movement of the screw with respect to the bone  
29 fixture apparatus.

30

31 Typically, inserting a screw displaces some of the  
32 pliable material, which expands against a surface of

1 the bone fixture apparatus. This expansion force  
2 helps to hold the screw stationary with respect to  
3 the bone fixture apparatus. In such examples, the  
4 pliable material is typically contained within a  
5 containment area in the bone fixture apparatus, so  
6 that when the pliable material expands it pushes  
7 against the walls of the containment area and  
8 increases the grip between the bone fixture  
9 apparatus and the screw. In certain embodiments the  
10 material can be self-expanding, and this can  
11 increase the grip of the screw on the bone fixture  
12 apparatus. In other embodiments of the invention,  
13 the screw can cut threads in the pliable material  
14 and this can help to hold the screw steady relative  
15 to the bone fixture apparatus. Preferably the  
16 pliable material is contained or received within the  
17 hole that also accommodates the fixing device, and  
18 the act of driving the fixing device through the  
19 pliable material in the hole expands or deforms the  
20 pliable material within the hole and holds the  
21 fixing therein.

22  
23 According to a further aspect of the present  
24 invention, there is provided the use of a pliable  
25 material in co-operation with a bone fixture  
26 apparatus in a method of supporting a bone fracture.

27  
28 According to a further aspect of the present  
29 invention, there is provided a pliable insert for  
30 engaging a fixing device for a bone fixture  
31 apparatus.

32

1 According to a further aspect of the present  
2 invention, there is provided a bone fixing apparatus  
3 having at least one hole, wherein the hole is  
4 provided with a tapered inner surface.  
5

6 An embodiment of the invention will now be described  
7 by way of example only and with reference to the  
8 following drawings, in which:-  
9

10 Fig 1 shows a cross-sectional view of an intra-  
11 medullary nail inside the medullary canal of a  
12 broken bone;

13 Fig 2 shows a side view of an intra-medullary  
14 nail attached to a jig;

15 Fig 3 shows a cross-sectional view of an intra-  
16 medullary nail filled with a pliable material;

17 Fig 4 shows a cross-sectional view of the  
18 apparatus of Fig 3 with a screw extending  
19 through the nail;

20 Fig 5 shows a cross-sectional view of an intra-  
21 medullary nail on the interior of which is an  
22 annulus of pliable material;

23 Fig 6 shows the cross-sectional view of the  
24 apparatus of Fig 5 with a screw extending  
25 through the nail;

26 Fig 7 shows a cross-sectional view through a  
27 solid nail in accordance with another  
28 embodiment;

29 Fig 8 shows a cross-sectional view through a  
30 solid nail in accordance with a further  
31 embodiment;

1           Fig 9 shows a cross-sectional view through a  
2           tubular nail in accordance with another  
3           embodiment;  
4           Fig 10 shows a cross-sectional view through a  
5           tubular nail in accordance with a further  
6           embodiment;  
7           Fig 11 is a front view of a bone plate  
8           according to the invention;  
9           Fig 12 is an enlarged view of one of the holes  
10          in the bone plate of Fig 11;  
11          Fig 13 is a cross-sectional view taken along  
12          the line A-B of Fig 12;  
13          Fig 14 is a cross-sectional view of the bone  
14          plate of Fig 11 having a pliable insert;  
15          Fig 15 is a cross-sectional view of the bone  
16          plate of Fig 11 having an alternative  
17          embodiment of insert;  
18          Fig 16 shows a cross-sectional view of the Fig  
19          14 bone plate and pliable insert, having a  
20          screw driven through the insert; and  
21          Figs 17 and 18 show cross-sectional views of a  
22          further embodiment of bone plate and insert.

23

24          Referring now to the drawings, Fig 1 shows a bone  
25          fixture apparatus in the form of an intra-medullary  
26          nail 10, which is inserted inside the medullary  
27          canal 12 of a broken bone 14. The broken bone 14  
28          consists of two bone portions 16A and 16B. The  
29          intra-medullary nail 10 extends substantially the  
30          whole length of the medullary canal 12.

31

1 Fig 2 shows an intra-medullary nail 10 attached to a  
2 jig 20 at one end. Both the nail 10 and the jig  
3 have holes 18, 28 at each of their ends. Each hole  
4 18 in the nail 10 is aligned with a respective hole  
5 28 in the jig. A screw 26 is shown inserted through  
6 a hole 18 in the nail 10, and a hole 28 in the jig  
7 20.

8  
9 One embodiment of the invention is illustrated in  
10 Figs 3 and 4.

11  
12 Fig 3 shows a hollow intra-medullary nail 10 of the  
13 rolled tube type, which has lateral holes 18 aligned  
14 at the same axial position on each side at the end  
15 of the nail 10. The nail 10 is entirely filled with  
16 a pliable material comprising a cylindrical insert  
17 30 of polyethylene, which is inserted into the end  
18 of the nail 10.

19  
20 In use, the nail 10 is inserted into the medullary  
21 canal of the bone portions 16A, 16B to be aligned.  
22 The cylinder 30 of pliable material is inserted into  
23 the nail 10 either before or after the nail 10 is  
24 inserted into the medullary canal. The nail 10 is  
25 then optionally attached at one end to a jig 20. At  
26 least one screw 26 is driven into the bone on each  
27 side of the break, at positions aligned with holes  
28 in the jig 20 and holes 18 the nail 10. The screws  
29 26 pass through the holes 28 in the jig 20 and the  
30 holes 18 in the nail 10, and engage the cylinder 30  
31 of pliable material. The screw threads of screws 26  
32 cut into the pliable material 30 as the screws are

1 driven into it, thereby ensuring a firm grip of the  
2 screw by the cylinder 30. The pliable material of  
3 the cylinder 30 is also displaced radially outwards  
4 and expands against the inside surface of the nail  
5 10, thereby pressing the cylinder 30 against the  
6 nail 10. The increased grip between the screw 26  
7 and the cylinder 30 and between the cylinder 30 and  
8 the nail 10 helps to keep the screws 26 stationary  
9 with respect to the nail 10, thereby preventing or  
10 restraining movement of the nail in the bone 16  
11 which can disrupt the healing process.

12

13 It should be understood that the use of the jig is  
14 not essential for the working of this invention; it  
15 is merely a useful tool to help to locate the holes  
16 for the screws in alignment with the holes in the  
17 nail 10.

18

19 Fig 4 shows the apparatus of Fig 3, with a screw 26  
20 inserted through the holes 18 in the nail 10, and  
21 through the cylinder 30. The pliable material of  
22 the cylinder 30 has been squeezed outwards against  
23 the inner surface of the nail 10 by the movement of  
24 the screw 26, and exerts a force on the inside  
25 surface of the nail 10 to keep the nail 10 in place.

26

27 An alternative embodiment of the invention is  
28 described in Figs 5 and 6. This embodiment is  
29 similar to that of Figs 3 and 4, except that the  
30 pliable material is in the form of a liner or sleeve  
31 32 that lines the inside surface of the nail 10 as



1 shown in Fig 5, instead of filling the entire cross-  
2 section.

3  
4 In use, the nail 10 is inserted into the medullary  
5 canal as before. A hollow sleeve 32 of pliable  
6 material is inserted into the nail 10 either before  
7 or after the nail 10 is placed into the canal. The  
8 nail 10 is then attached at one end to a jig 20. At  
9 least one screw 26 is driven into the bone on each  
10 side of the break at positions aligned with holes 28  
11 in the jig 20 and holes 18 in the nail 10. Screws  
12 26 are inserted through the hole 28 in the jig 20  
13 and the hole 18 in the nail 10, and the screws 26  
14 cut threads into the cylinder 32 of pliable  
15 material, which helps to keep the screw 26 and the  
16 intra-medullary nail 10 firmly connected with  
17 reduced scope for movement of the nail 10 in the  
18 bone during the healing process.

19  
20 Fig 6 shows the embodiment of Fig 5 with a screw  
21 inserted through the nail 10 and through the  
22 cylinder 32 of pliable material.

23  
24 The purpose of the pliable material is to hold the  
25 screw in position and any shape/amount/type of  
26 pliable material that achieves this function can be  
27 used. It is generally useful if a part of the  
28 pliable material forms, covers or surrounds a screw-  
29 receiving hole in the intra-medullary nail so that  
30 the screw self-taps into it, forming its own threads  
31 or hole in the pliable material. It is advantageous  
32 but not necessary for the pliable material to be

1 pressed against the nail, through either  
2 displacement by the screw, and/or the pliable  
3 material itself being self-expanding.

4  
5 Figs 7 and 8 show how the invention can be applied  
6 to a solid nail 50, which has a lateral bore 58 to  
7 receive a screw. The bore 58 is lined with a sleeve  
8 52 in the fig 7 embodiment that is formed from  
9 pliable material (in this case the pliable material  
10 is a polyamide). The sleeve 52 is deformed by the  
11 screw threads as the screw penetrates the bore, and  
12 this enhances the grip between the nail and the  
13 screw. The sleeve 52 can be replaced by one or more  
14 annular rings 54 that can usefully be positioned at  
15 opposite ends of the bore 58 as shown in the Fig 8  
16 embodiment.

17  
18 The annular rings 54 or the sleeve 52 can be used in  
19 a tubular nail 10 as shown in Fig 9 and Fig 10.  
20 It is not important which particular pliable  
21 material is used; suitable materials include metals,  
22 polymers (absorbable/non-absorbable), non-metallic  
23 materials (e.g. carbon complexes) and naturally  
24 occurring materials (e.g. collagen constructs).

25  
26 It could be advantageous for the patient if only  
27 small quantities of pliable material are used, so as  
28 to keep the amount of foreign agents in his body to  
29 a minimum. Typically pliable materials that are  
30 biodegradable are preferred.

31

1 A further alternative embodiment of the invention is  
2 shown in Figs 11 to 14. Fig 11 shows a bone plate  
3 60 which has a series of oval holes 62 and circular  
4 holes 64 along its length; each hole extends through  
5 the plate from an upper surface 66 of the plate to a  
6 lower surface 68. One of the circular holes 64' is  
7 shown in more detail in Figs 12 and 13.

8  
9 As best seen in Fig 13, the hole 64' has walls 65  
10 which are tapered so that they are inclined relative  
11 to each other and to the upper and lower surfaces  
12 66, 68 of the bone plate. The hole 64' also has a  
13 central axis X.

14  
15 The wall 65 of the hole 64' inclines radially  
16 inwardly towards the hole axis X from the top  
17 surface 66 to an apex 70, from where the wall 65  
18 inclines radially outwards to the lower surface 68.  
19 The apex 70 is located slightly below the midpoint  
20 of the hole 64'. The cross-section of the hole 64'  
21 thus generally resembles an hourglass.

22  
23 Referring now to Fig 14, a pliable insert 72 also  
24 having the form of an hourglass is shown inserted  
25 into the hole 64'. The pliable insert 72 is formed  
26 so that it fits inside the hole in a clearance fit.  
27 Ideally, once inserted there should be essentially  
28 no gap between the insert 72 and the wall 65 of the  
29 bone plate 60.

30  
31 The pliable insert 72 can typically be squeezed into  
32 the hole 64'. For example, the material of the

1     pliable insert 72 could be chosen such that a slight  
2     heating of the pliable insert 72 would make the  
3     insert 72 compressible to fit in the hole 64'.

4     Other embodiments can be envisaged where the pliable  
5     insert 72 is formed in the hole 64' by melting the  
6     pliable material and allowing it to set within the  
7     hole.

8  
9     Once inserted, the insert 72 is retained in the hole  
10    64' by the hourglass-shape of the walls 65. The  
11    insert 72 would typically be inserted into the hole  
12    64' before surgery, but in certain circumstances the  
13    insert 72 can be inserted peroperatively.

14  
15    The interior surfaces of the other holes 62, 64 in  
16    the bone plate 60 have a similar shape.

17  
18    Fig 15 shows the hole 64' of the bone plate 60  
19    having an alternative embodiment of pliable insert  
20    76, typically made from a resilient material such as  
21    a resilient plastics material or a rubber. The  
22    lower end 78 (defined with reference to the bone  
23    plate) of the insert 76 has wedge-shaped slits 80  
24    cut between adjacent legs. The slits 80 are aligned  
25    parallel to the axis X, with the tip of each cut-out  
26    wedge at the upper end of each slit 80, giving a  
27    pleated effect. The legs of the insert 76 do not  
28    extend all of the way to the lower surface 68 of the  
29    plate 60 in this embodiment. The upper end 77 of  
30    the insert 76 mirrors the shape of the upper parts  
31    of the walls 65.

32

1 The insert 76 is engaged in the hole by squeezing  
2 the legs at the lower end 78 of the insert 76 so  
3 that the slits 80 are compressed together, the legs  
4 are parallel to one another, and the lower end 78 of  
5 the insert 76 is squeezed into a generally  
6 cylindrical arrangement that can pass the apex 70 of  
7 the walls 65. Thus, the insert 76 can be squeezed  
8 into the hole 64' and once in position, the  
9 resilience of the pliable insert 76 will cause the  
10 slits 80 to assume their original wedge-like shapes,  
11 splaying the legs outwards, and the lower end of the  
12 insert 76 will be trapped below the apex 70, thus  
13 retaining the insert 76 in the hole 64', as shown in  
14 Fig 15.

15

16 This embodiment provides the advantage that the  
17 insert 76 can be inserted into the hole 64' without  
18 any external heating or special application of extra  
19 force, so the insert 76 can easily be inserted into  
20 any suitable hole at any time before or during the  
21 operation with an easy press-fit. Driving a fixing  
22 device such as a screw through the insert 76 will  
23 keep the legs splayed and securely anchor the insert  
24 76 within the hole 64'.

25

26 Fig 16 shows the bone plate 60 and insert 72 of Fig  
27 14, with a screw 82 screwed into the insert 72. The  
28 screw 82 has a head 84 and a shaft 86, both of which  
29 are threaded. The screw 82 is inserted far enough  
30 into the insert 72 such that the head 84 is threaded  
31 into the insert 72 in addition to the shaft 86. The  
32 threads of the screw 82 cut into the bone (not

1 shown) and the screw 82 acts as a fixing device to  
2 attach the bone plate 60 to the bone.

3

4 The axis of the screw 82 is shown by the line Y in  
5 Fig 16; it is not co-axial with the axis X of the  
6 hole 64' but is inclined relative thereto. The  
7 invention provides the significant advantage over  
8 conventional bone fixing devices that it allows the  
9 selection of the angle of insertion of the screw 82,  
10 without the surgeon being forced to change the  
11 attitude or orientation of the hole or the bone  
12 plate 60. Examples of several possible screw  
13 orientations are shown as dotted lines S, T, U, V in  
14 Figs 14 and 15. The screw position/angle is  
15 typically chosen prior to the insertion of the screw  
16 82. The angle of screw insertion would typically be  
17 influenced by the diameter of the leading thread of  
18 screw, the core diameter of the screw, and the shape  
19 and diameter of the screw head.

20

21 The insert 76 of the Fig 15 embodiment can receive a  
22 screw in just the same way as shown in Fig 16 for  
23 the insert 72.

24

25 The inserts 72, 76 could either be formed with one  
26 or more predrilled holes for insertion of screws, or  
27 alternatively, the inserts 72, 76 could be solid and  
28 the screw holes could be drilled according to the  
29 surgeon's requirements or judgement during the  
30 operation. An advantage of pre-drilled holes is  
31 that this eliminates the possibility that the  
32 surgeon might drill through the insert and into the

1 bone plate. On the other hand, if a hole is drilled  
2 in a solid insert during the operation, the surgeon  
3 has complete freedom of choice of hole angle.

4  
5 The embodiments described in Figs 14 to 16 are  
6 adapted for circular holes and have axial symmetry,  
7 so that the inserts 72, 76 can be rotated in their  
8 respective holes. Rotation of the insert 72, 76  
9 sweeps the angle of the hole around in an arc,  
10 allowing the surgeon even more freedom of choice to  
11 insert the screw 82 at the required angle, or in the  
12 required direction.

13  
14 Fig 17 shows a yet further alternative embodiment,  
15 wherein a bone plate 90 has an upper surface 92 and  
16 a lower surface 94. The bone plate 90 has holes 96  
17 (only one shown) having tapered walls. The hole 96  
18 is frusto-conical, the narrower end being at the  
19 lower surface 94 and the wider end being at the  
20 upper surface 92. Thus, the walls of the hole 96  
21 are inclined radially inwards from the upper surface  
22 92 to the lower surface 94. Unlike the embodiments  
23 of Figs 11 to 16, there is no apex in the surface of  
24 the walls, the inclination being typically  
25 continuous between the upper and lower surfaces 92,  
26 94, although an annular stop could be formed at the  
27 lower surface 94 if desired (not shown).

28  
29 The hole 96 has a pliable insert 98 inserted  
30 therein. The insert 98 is also in the form of a  
31 trapezium, being dimensioned to fit the shape of the  
32 hole 96, so that the insert 98 fits in and fills the

1 hole 96 as shown in Fig 17. The angle of  
2 inclination of the sides is exaggerated in figure  
3 17, and in practice any significant inclination of  
4 the walls is useful, as it permits the insert to  
5 enter and leave the hole only through the wider  
6 aperture of the top surface 92.

7  
8 In certain simple embodiments of this version, the  
9 sidewalls (i.e. not the upper and lower surfaces) of  
10 both of the insert 98 (typically) and the hole 96  
11 can be plain, but in the more advanced embodiment  
12 shown the sidewall of at least the hole 96 is screw  
13 threaded in order to grip the insert 98 more  
14 securely. The outer wall of the insert can also be  
15 threaded as shown in this embodiment, but in other  
16 versions, it is sufficient for the thread to be cut  
17 into the insert 98 by the thread on the hole 96  
18 during insertion of the insert 98 into the hole 96.  
19 In this example, the coupled threads are designated  
20 100 in the drawing. Therefore, this embodiment  
21 provides a pliable insert that can be screwed into a  
22 bone plate by engaging the threads of the plate  
23 aperture and the insert. The insert 98 can be  
24 screwed into holes in conventional bone plates where  
25 required in order to fix the insert more securely to  
26 the plate. Thus, when the screw or other bone  
27 fixing device is driven through the insert 98, the  
28 consequent deformation of the insert 98 pushes the  
29 plastic of the insert even more firmly into the  
30 threads on the inner surface of the hole 96, thereby  
31 reducing the possibility of the insert allowing any



1 play of the plate and fixing after the two are  
2 finally connected.

3

4 As with previous embodiments, the screws or other  
5 fixings can be driven through the solid plug of the  
6 insert 98 or alternatively the insert 98 can have  
7 pre-drilled holes to guide insertion of the fixings.  
8 Naturally, with pre-drilled holes in the insert 98,  
9 the insert 98 can be rotated to select a suitable  
10 path for the fixing into the bone. This feature  
11 can be especially useful if part of the bone is  
12 comminuted, the bone portions in these parts being  
13 very tiny, and where especially accurate selection  
14 of the angle of insertion of the screws is required.  
15 In some embodiments, some of the holes in the bone  
16 plate could be used with screws directly, and the  
17 holes relating to the comminuted parts of the  
18 fracture could be filled with an insert according to  
19 the invention.

20

21 Fig 18 shows the Fig 17 insert 98 with a screw 82  
22 driven therethrough.

23

24 The invention allows the use of smaller screws, as  
25 in this invention, the size of the screw is not  
26 defined by the size of the hole in the bone plate;  
27 any size of screw smaller than the hole can be  
28 chosen. Again, this may be particularly useful for  
29 comminuted fractures.

30

31 If the conventional bone plate has holes with  
32 parallel walls, a correspondingly parallel-walled

1     insert could be provided. Therefore, this invention  
2     also provides embodiments which can be used in  
3     conjunction with conventional bone plates/  
4     intramedullary nails, as and where required, to give  
5     the advantage of being able to select the angle of  
6     insertion of the hole and the required screw size.

7  
8     It should be noted that the non-parallel sided  
9     designs of insert and bone fixture apparatus in the  
10    embodiments of Figs 11 to 17 could equally be  
11    applied to the intra-medullary nail embodiments;  
12    these do not necessarily relate only to bone plates.

13  
14    It should also be noted that in the embodiments of  
15    Fig 17 and 18 it is not necessary for the insert 98  
16    to be threaded, and the thread can be cut into the  
17    insert 98 by the act of screwing a blank insert 98  
18    into the hole.

19  
20    Modifications and improvements can be incorporated  
21    without departing from the scope of the invention.  
22    For example, the bone fixture apparatus may be a  
23    bone plate, a fracture brace or any other kind of  
24    bone fixture apparatus; the invention does not  
25    necessarily relate to intra-medullary nails.

26  
27    Other types of pliable material may be used beyond  
28    the types specifically mentioned above.

29  
30    The bone fixture apparatus does not necessarily  
31    include holes. For example, the pliable material  
32    could be bonded to the bone fixture apparatus and a

- 1     fixing device could be engaged with the pliable
- 2     material alone.
- 3

1     Claims

2

3     1.    A bone fixture apparatus having a pliable  
4     material for engaging a fixing device.

5

6     2.    A bone fixture apparatus as claimed in claim 1,  
7     wherein the pliable material is deformable.

8

9     3.    A bone fixture apparatus as claimed in claim 1  
10    or claim 2, wherein the pliable material comprises  
11    an insert.

12

13    4.    A bone fixture apparatus as claimed in any  
14    preceding claim, wherein the form of the pliable  
15    material is selected from the group consisting of a  
16    hollow sleeve, at least one ring, a plug, a coating  
17    and a liner.

18

19    5.    A bone fixture apparatus as claimed in any  
20    preceding claim, wherein the pliable material is  
21    received in a threaded aperture in the apparatus.

22

23    6.    A bone fixture apparatus as claimed in any  
24    preceding claim, wherein the pliable material is  
25    settable.

26

27    7.    A bone fixture apparatus as claimed in any  
28    preceding claim, wherein the pliable material is  
29    expandable.

30

31    8.    A bone fixture apparatus as claimed in claim 7,  
32    wherein the pliable material is self-expanding.

1

2 9. A bone fixture apparatus as claimed in any  
3 preceding claim, wherein the pliable material lines  
4 at least a part of the inside of the bone fixture  
5 apparatus.

6

7 10. A bone fixture apparatus as claimed in any  
8 preceding claim, wherein the pliable material is  
9 located within a passage of the bone fixture  
10 apparatus.

11

12 11. A bone fixture apparatus as claimed in claim  
13 10, wherein the pliable material fills the  
14 transverse cross-sectional area of the passage.

15

16 12. A bone fixture apparatus as claimed in any  
17 preceding claim, wherein the bone fixture apparatus  
18 has at least one hole to receive a respective fixing  
19 device and wherein the pliable material is located  
20 in a region of the hole.

21

22 13. A bone fixture apparatus as claimed in claim  
23 12, wherein the pliable material lines the inside of  
24 the hole.

25

26 14. A bone fixture apparatus as claimed in claim 12  
27 or claim 13, having a cylindrical passage through  
28 the bone fixture apparatus terminating in a  
29 respective hole at each end of the passage.

30

31 15. A bone fixture apparatus as claimed in claim  
32 14, wherein the pliable material is located at each

1 end of the passage, around the inside surface of the  
2 passage.

3

4 16. A bone fixture apparatus as claimed in claim 14  
5 or claim 15, wherein the entire passage is filled  
6 with pliable material.

7

8 17. A bone fixture apparatus as claimed in claim 12  
9 or claim 13, wherein the bone fixture apparatus is  
10 hollow and the pliable material is in the form of a  
11 sleeve or cylinder that spans the gap between holes  
12 in opposite sides of the bone fixture apparatus.

13

14 18. A bone fixture apparatus as claimed in any of  
15 claims 12 to 17, wherein the hole is tapered.

16

17 19. A bone fixture apparatus as claimed in any of  
18 claims 12 to 18, wherein the pliable material is in  
19 the form of an insert which fills the hole.

20

21 20. A bone fixture apparatus as claimed in claim  
22 19 when dependent on claim 18, wherein the insert  
23 tapers to match the shape of the hole.

24

25 21. A bone fixture apparatus as claimed in claim 19  
26 or claim 20, wherein the hole and the insert are  
27 frusto-conical.

28

29 22. A bone fixture apparatus as claimed in any of  
30 claims 19 to 21, wherein the insert has a  
31 compressible portion, which can be compressed to fit  
32 through a narrow section of the hole.

1

2 23. A bone fixture apparatus as claimed in claim  
3 22, wherein the compressible portion has slits.

4

5 24. A bone fixture apparatus as claimed in claim 22  
6 or claim 23, wherein the compressible portion is  
7 adapted to splay outwards to retain the insert in  
8 the hole after insertion.

9

10 25. A bone fixture apparatus as claimed in any of  
11 claims 19 to 24, wherein the insert is rotatable in  
12 the hole.

13

14 26. A bone fixture apparatus as claimed in any of  
15 claims 19 to 25, wherein the hole is provided with  
16 internal screw threads.

17

18 27. A bone fixture apparatus as claimed in claim  
19 26, wherein the insert has external screw threads to  
20 engage the internal threads on the hole, such that  
21 the insert can be screwed into the hole.

22

23 28. A bone fixture apparatus as claimed in any of  
24 claims 19 to 27, wherein the insert has an aperture  
25 therethrough to receive a fixing device.

26

27 29. A bone fixture apparatus as claimed in any  
28 preceding claim, wherein the pliable material is  
29 contained within a containment area of the bone  
30 fixture apparatus.

31

1     30. A bone fixture apparatus as claimed in any  
2     preceding claim, wherein the pliable material is  
3     fixed to the bone fixture apparatus.

4

5     31. A bone fixture apparatus as claimed in any  
6     preceding claim, wherein the pliable material is  
7     selected from the group consisting of metals and  
8     polymers.

9

10    32. A bone fixture apparatus as claimed in any  
11    preceding claim, wherein the pliable material is  
12    selected from the group consisting of a plastics  
13    material, a carbon complex, polyethylene, nylon, and  
14    collagen and polypeptide constructs.

15

16    33. A bone fixture apparatus as claimed in any  
17    preceding claim, wherein the pliable material is  
18    biodegradable or bioabsorbable.

19

20    34. A bone fixture apparatus as claimed in any  
21    preceding claim, wherein the bone fixture apparatus  
22    comprises an intra-medullary nail.

23

24    35. A bone fixture apparatus as claimed in any of  
25    claims 1 to 33, wherein the bone fixture apparatus  
26    comprises a bone plate.

27

28    36. A method of supporting a fractured bone, the  
29    method comprising the steps of: attaching a bone  
30    fixture apparatus to the bone and engaging at least  
31    one fixing device with the bone, wherein the bone  
32    fixture apparatus is provided with a pliable



1 material and the fixing device is engaged with the  
2 pliable material.

3

4 37. A method as claimed in claim 36, wherein the  
5 fixing device is threaded, and wherein on insertion,  
6 the fixing device cuts threads in the pliable  
7 material to hold the fixing device relative to the  
8 pliable material.

9

10 38. A method as claimed in claim 36 or claim 37,  
11 wherein the insertion of the fixing device displaces  
12 some of the pliable material against the inside  
13 surface of the bone fixture apparatus.

14

15 39. A method as claimed in any of claims 36 to 38,  
16 wherein the pliable material is expandable upon  
17 application of pressure and the insertion of the  
18 fixing device causes the pliable material to expand.

19

20 40. A method as claimed in any of claims 36 to 39,  
21 wherein the pliable material is contained within a  
22 containment area in the bone fixture apparatus, and  
23 when the fixing device is inserted, the pliable  
24 material is displaced against the walls of the  
25 containment area.

26

27 41. A method as claimed in any of claims 36 to 40,  
28 wherein the fixing device is inserted through the  
29 bone and through at least one hole in the bone  
30 fixture apparatus.

31

1     42. A method as claimed in claim 41, wherein the  
2     pliable material lines the hole in the bone fixture  
3     apparatus.

4

5     43. A method as claimed in claim 41 or claim 42,  
6     wherein the pliable material is in the form of an  
7     insert which fills the hole in the bone fixture  
8     apparatus.

9

10    44. A method as claimed in claim 43, wherein the  
11    hole has internal threads, and the method includes  
12    the step of screwing the insert into the hole.

13

14    45. A method as claimed in claim 44, wherein the  
15    insert has external threads that engage with the  
16    threads on the hole.

17

18    46. A method as claimed in any of claims 43 to 45,  
19    wherein the insert is solid and an aperture is  
20    drilled in the insert during surgery.

21

22    47. A method as claimed in any of claims 43 to 45,  
23    wherein the insert has a predrilled aperture, which,  
24    in use, is inclined relative to the hole axis, and  
25    the method includes the step of rotating the insert  
26    to select the orientation of the aperture.

27

28    48. A method as claimed in any of claims 43 to 47,  
29    wherein the hole has an internal throat and the  
30    insert has a compressible portion, and the method  
31    includes the step of compressing the portion to fit

1 the insert at least partially through the throat of  
2 the hole.

3

4 49. A method as claimed in claim 48, wherein the  
5 compressible portion has legs which can be pushed  
6 together to compress the portion to fit the insert  
7 through the throat of the hole and which splay apart  
8 when in position in the hole to grip the hole.

9

10 50. The use of a pliable material in co-operation  
11 with a bone fixture apparatus in a method of  
12 supporting a bone fracture.

13

14 51. A pliable insert for engaging a fixing device  
15 for a bone fixture apparatus.

16

17 52. A pliable insert as claimed in claim 51,  
18 wherein the insert is deformable.

19

20 53. A pliable insert as claimed in claim 51 or  
21 claim 52, wherein the insert has external screw  
22 threads.

23

24 54. A pliable insert as claimed in any of claims 51  
25 to 53, wherein the insert is settable.

26

27 55. A pliable insert as claimed in any of claims 51  
28 to 54, wherein the insert is expandable.

29

30 56. A pliable insert as claimed in claim 55,  
31 wherein the insert is self-expanding.

32

1 57. A pliable insert as claimed in any of claims 50  
2 to 56, wherein the insert tapers bi-directionally to  
3 form a waist.

4

5 58. A pliable insert as claimed in any of claims 51  
6 to 57, wherein the insert has a compressible end.

7

8 59. A pliable insert as claimed in claim 58,  
9 wherein the compressible end has legs divided by  
10 slits, and wherein the legs can be pushed together  
11 to compress the end.

12

13 60. A pliable insert as claimed in claim 59,  
14 wherein the legs of the insert are adapted to splay  
15 outwards on the engagement of a fixing device with  
16 the insert.

17

18 61. A bone fixture apparatus as claimed in any of  
19 claims 51 to 60, wherein the insert has an aperture  
20 therethrough to receive a fixing device.

21

22 62. A pliable insert as claimed in any of claims 51  
23 to 61, wherein the insert comprises a material  
24 selected from the group consisting of metals and  
25 polymers.

26

27 63. A pliable insert as claimed in any of claims 51  
28 to 62, wherein the insert comprises a material  
29 selected from the group consisting of a plastics  
30 material, a carbon complex, polyethylene, nylon, and  
31 collagen and polypeptide constructs.

32

1     64. A pliable insert as claimed in any of claims 51  
2     to 63, wherein the insert is biodegradable.

3

4     65. A bone fixing apparatus having at least one  
5     hole, wherein the hole is provided with a tapered  
6     inner surface.

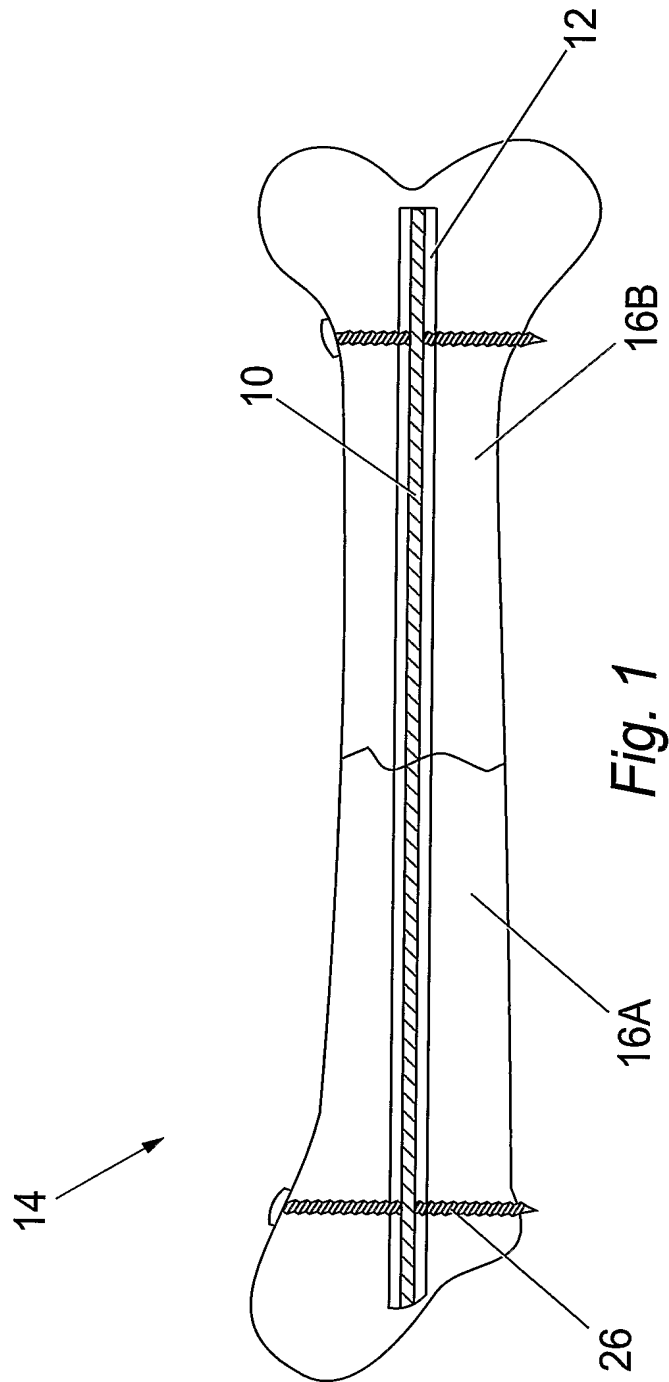
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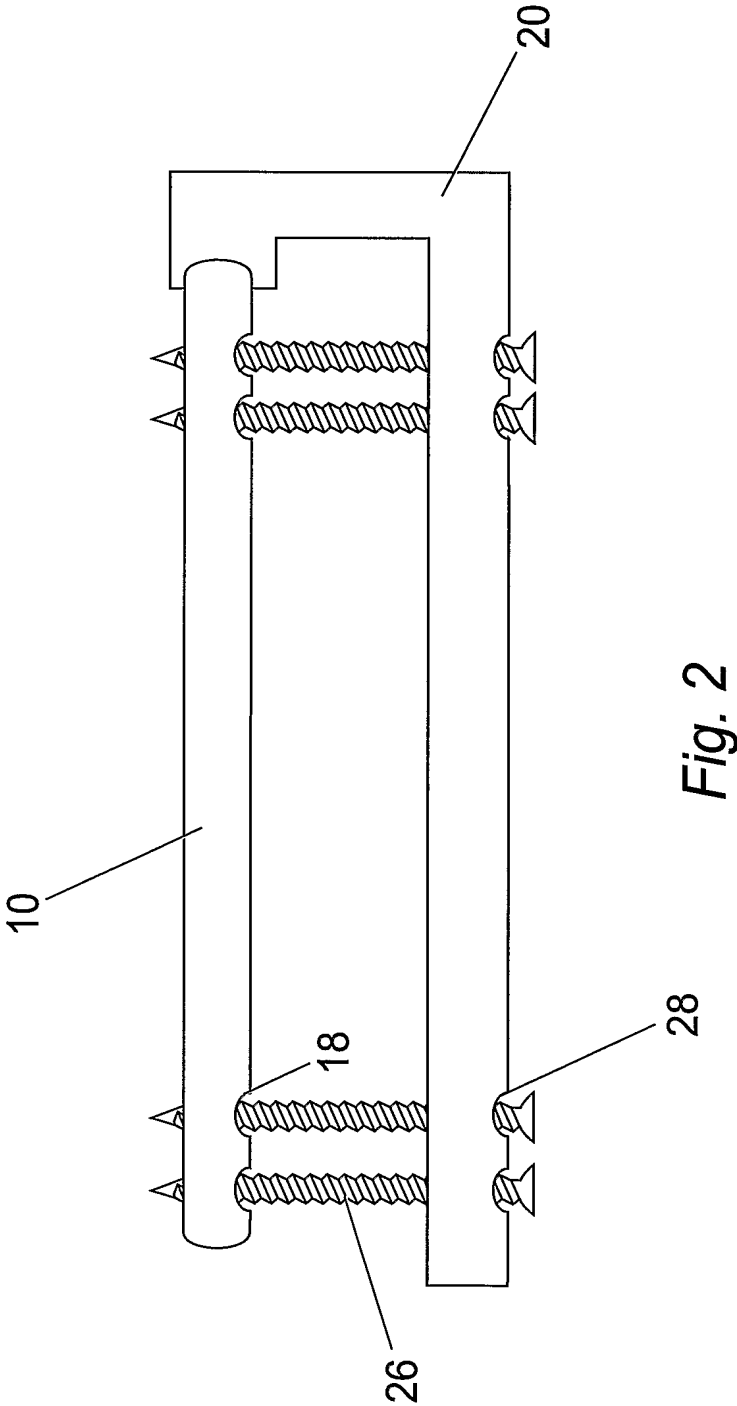
8     66. A bone fixing apparatus as claimed in claim 65,  
9     wherein the hole is bi-directionally tapered to form  
10    a throat.

11

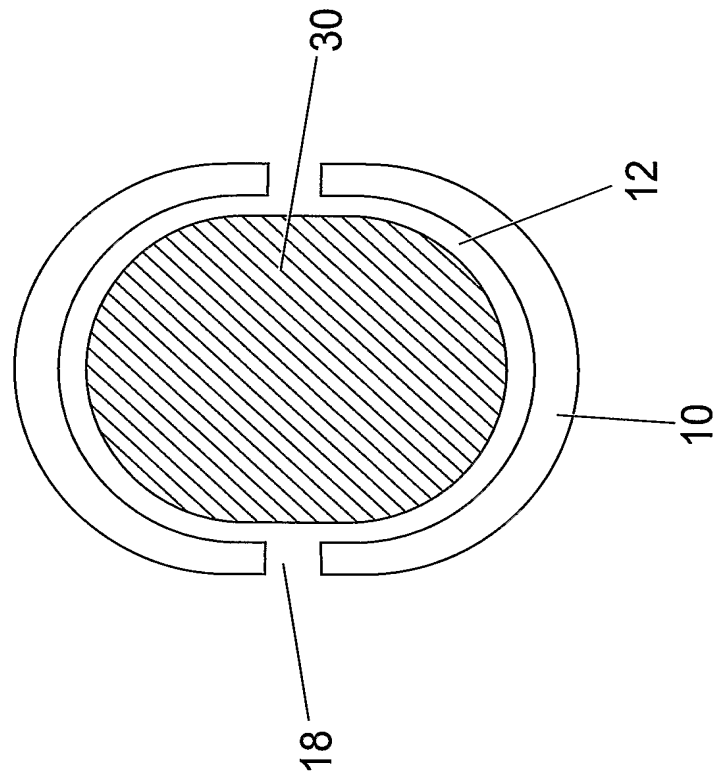
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3 / 13



*Fig. 3*



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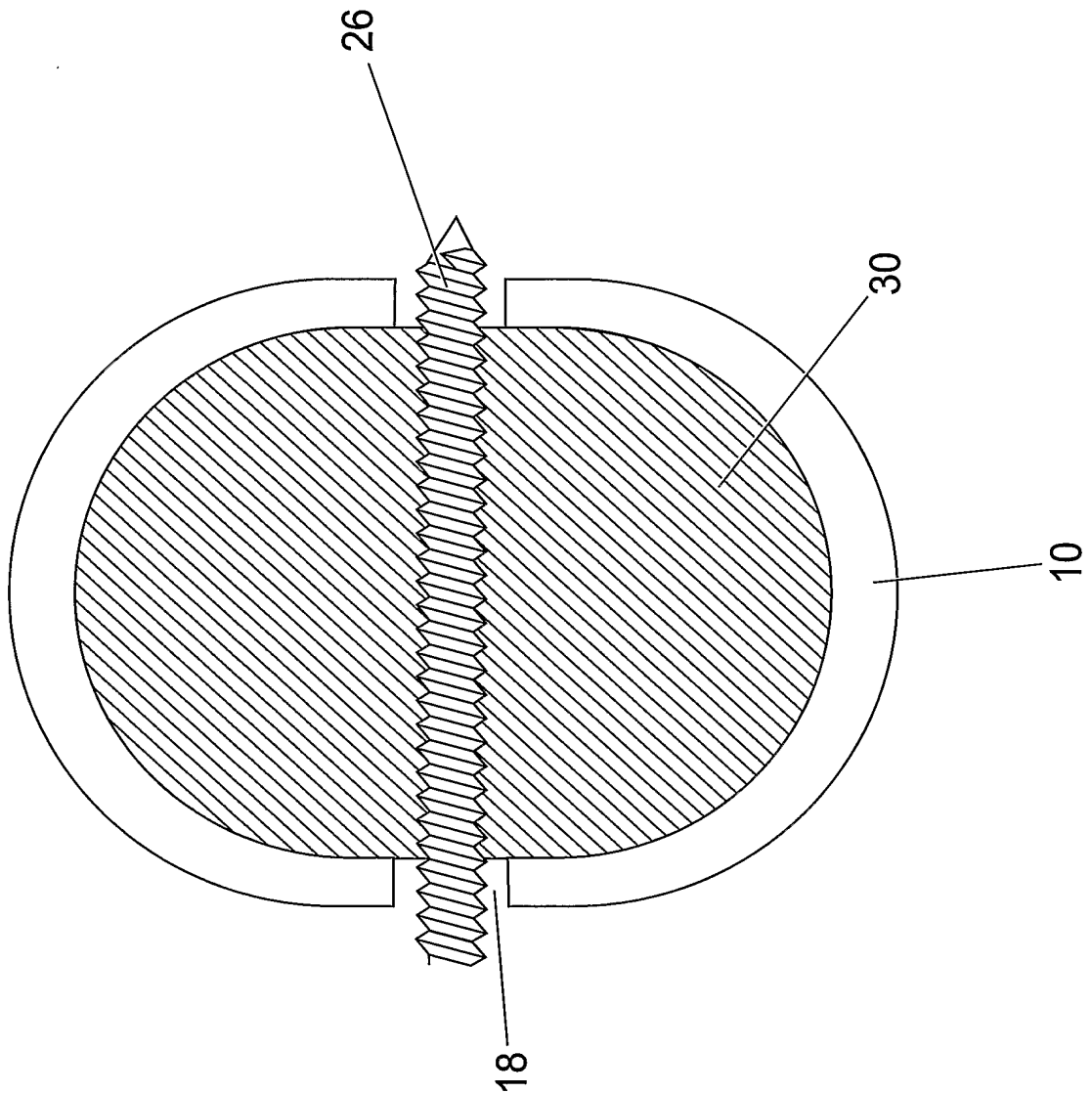


Fig. 4

5 / 13

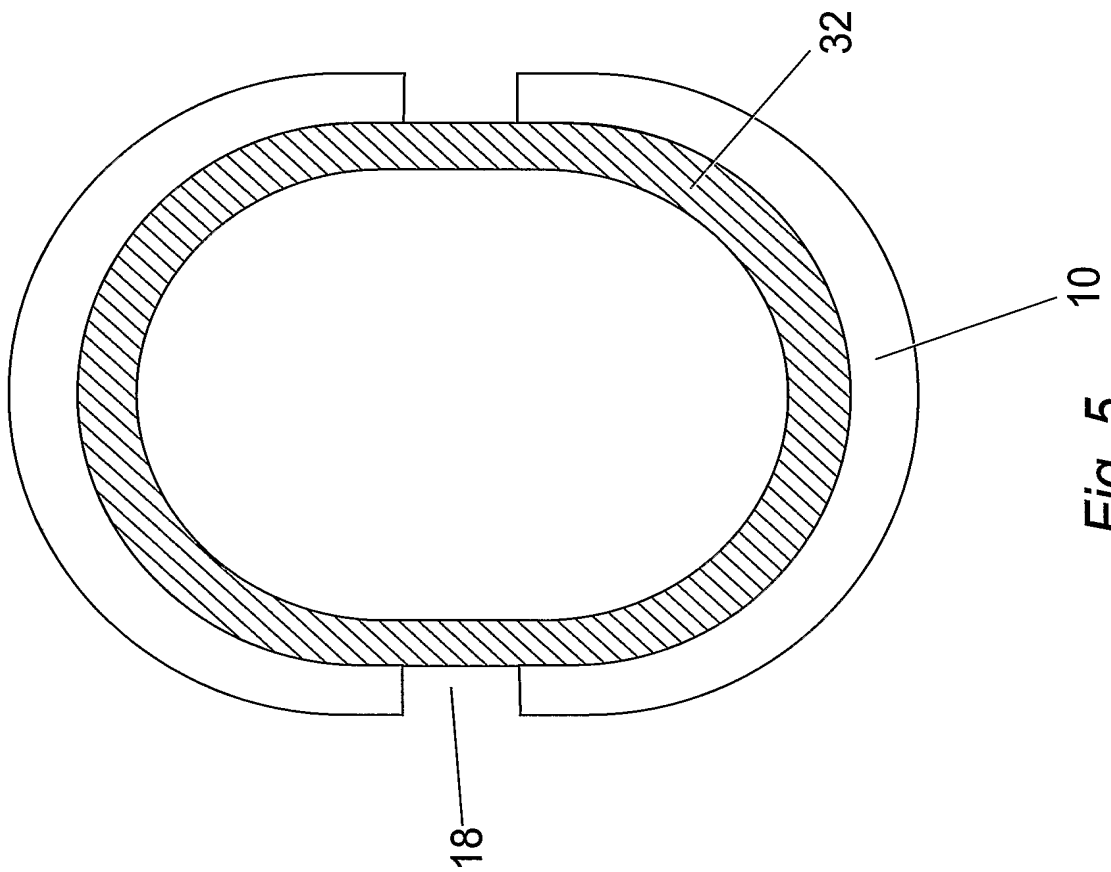
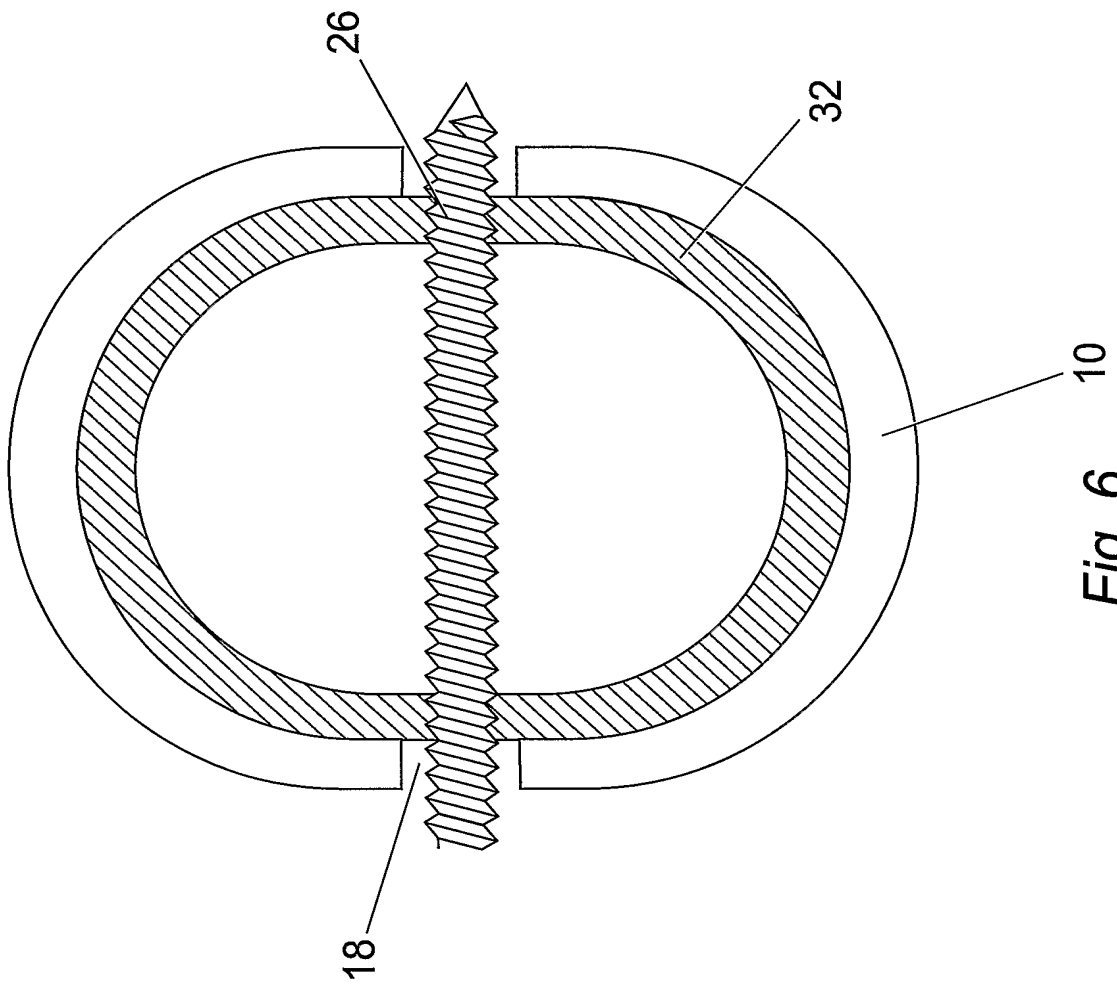


Fig. 5

6 / 13



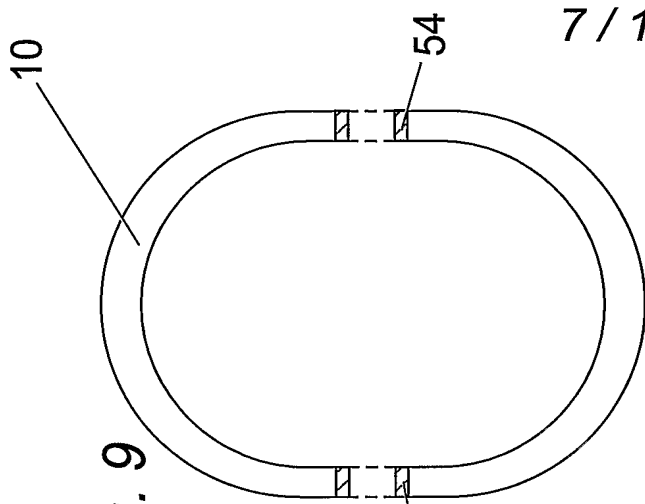


Fig. 9

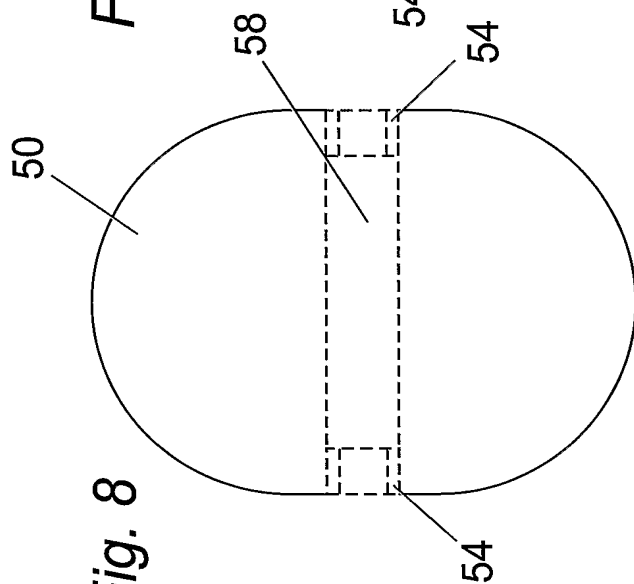


Fig. 8

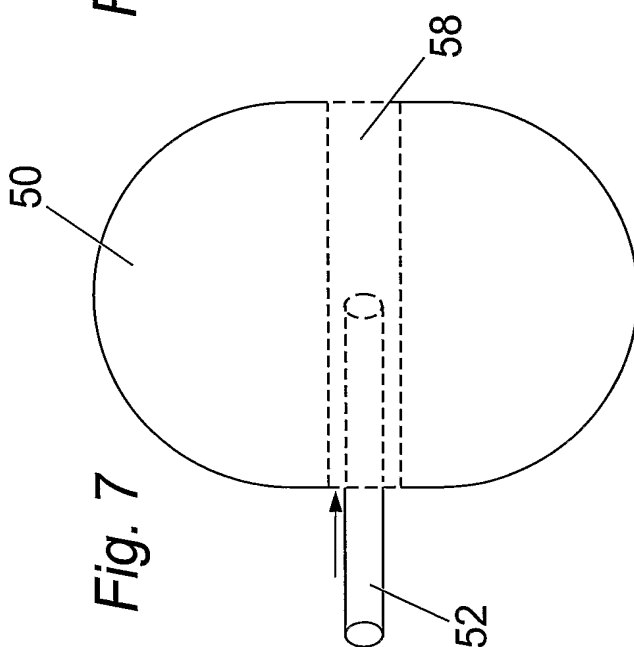


Fig. 7

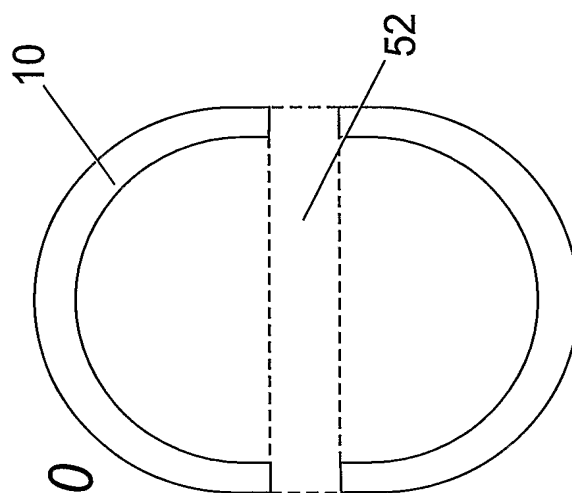


Fig. 10

8 / 13

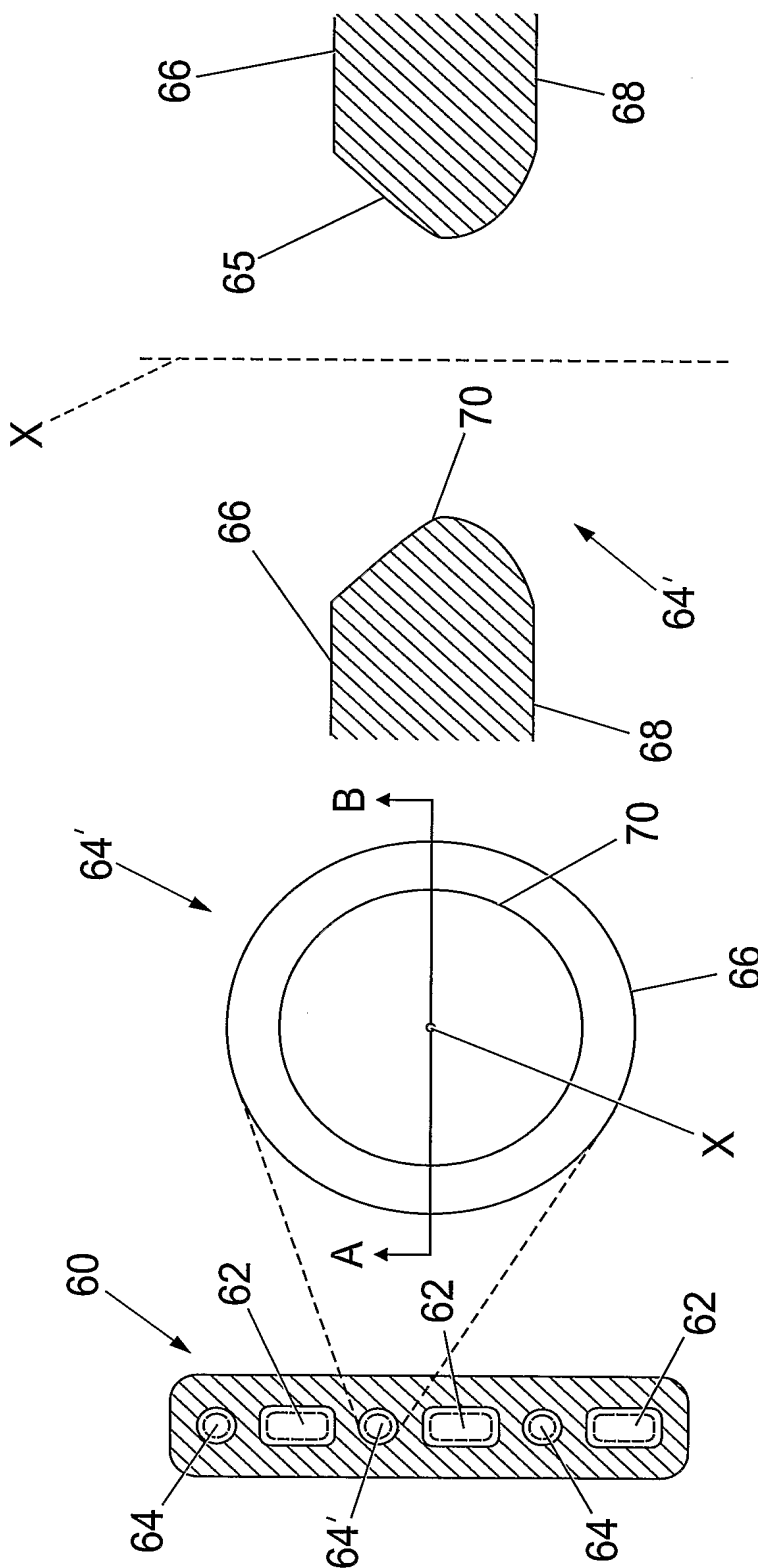


Fig. 13

Fig. 12

Fig. 11

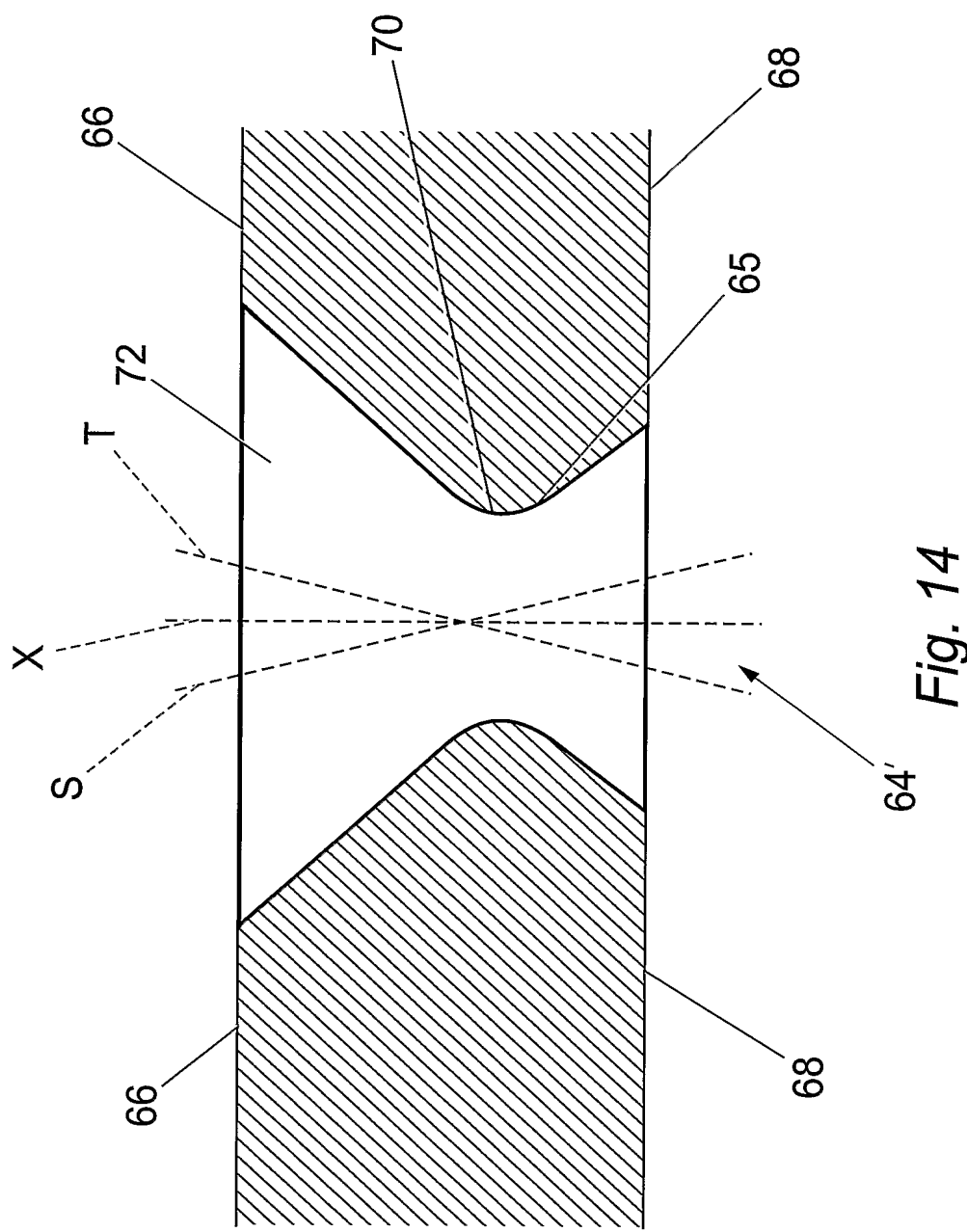
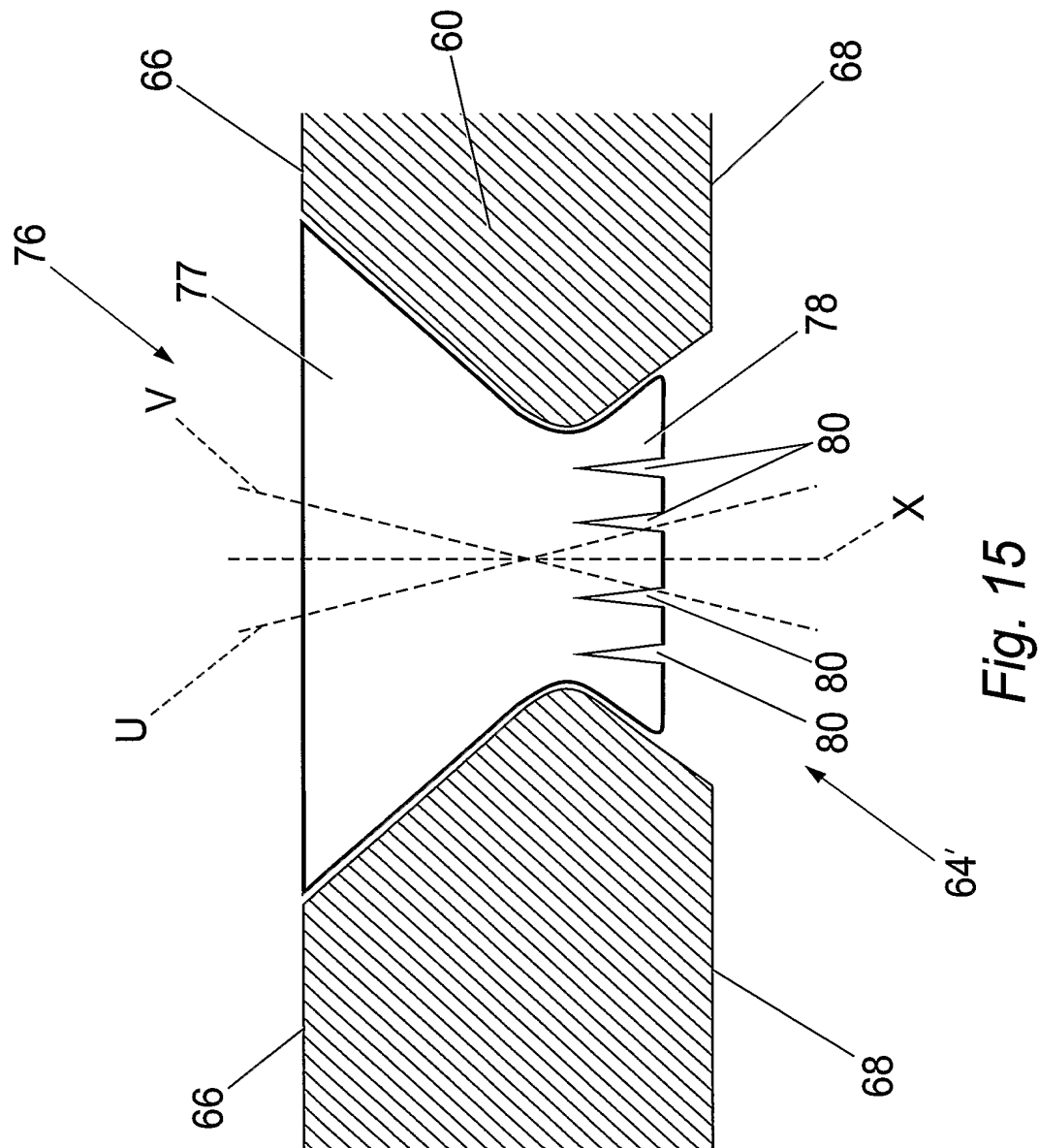


Fig. 14



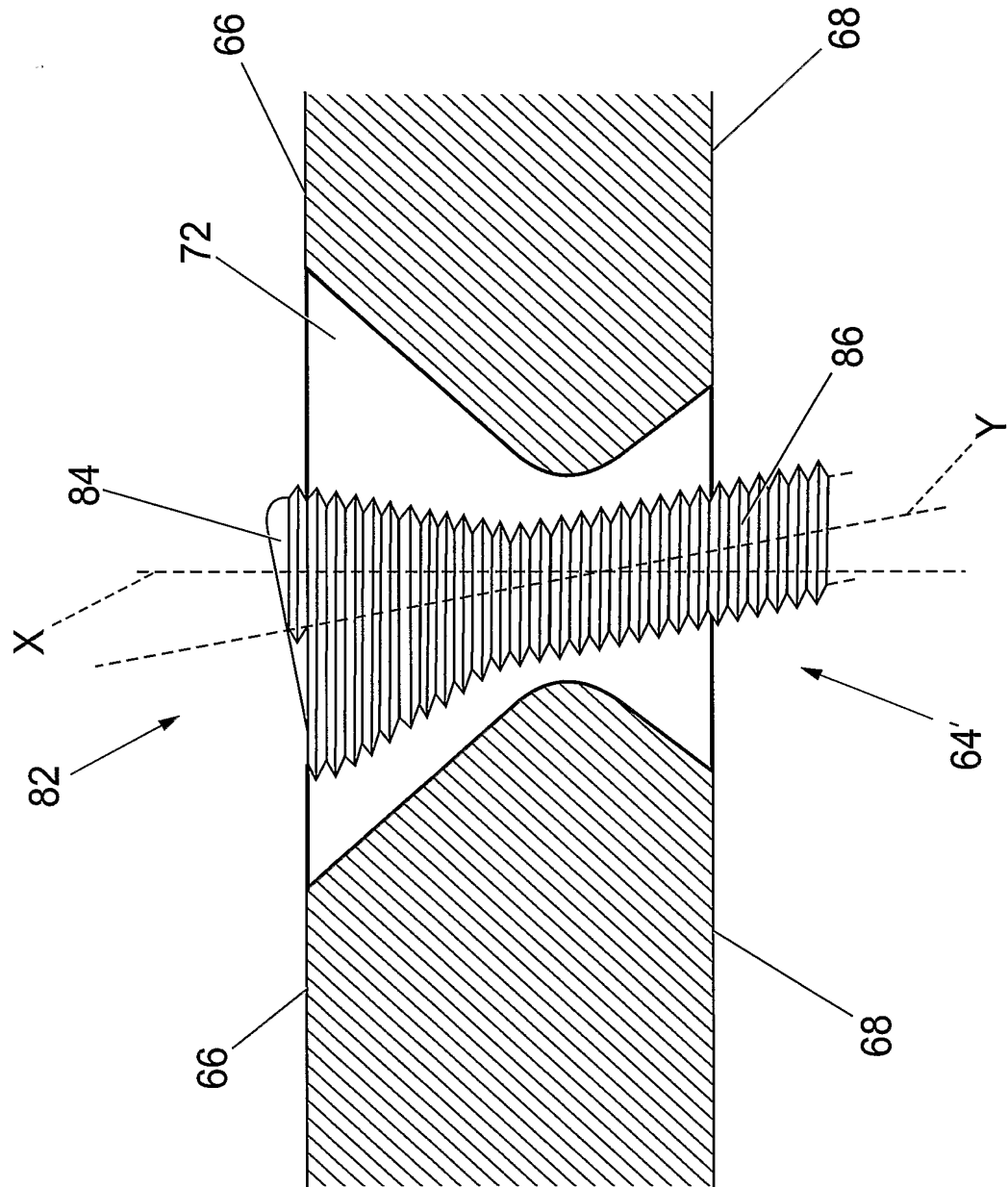


Fig. 16



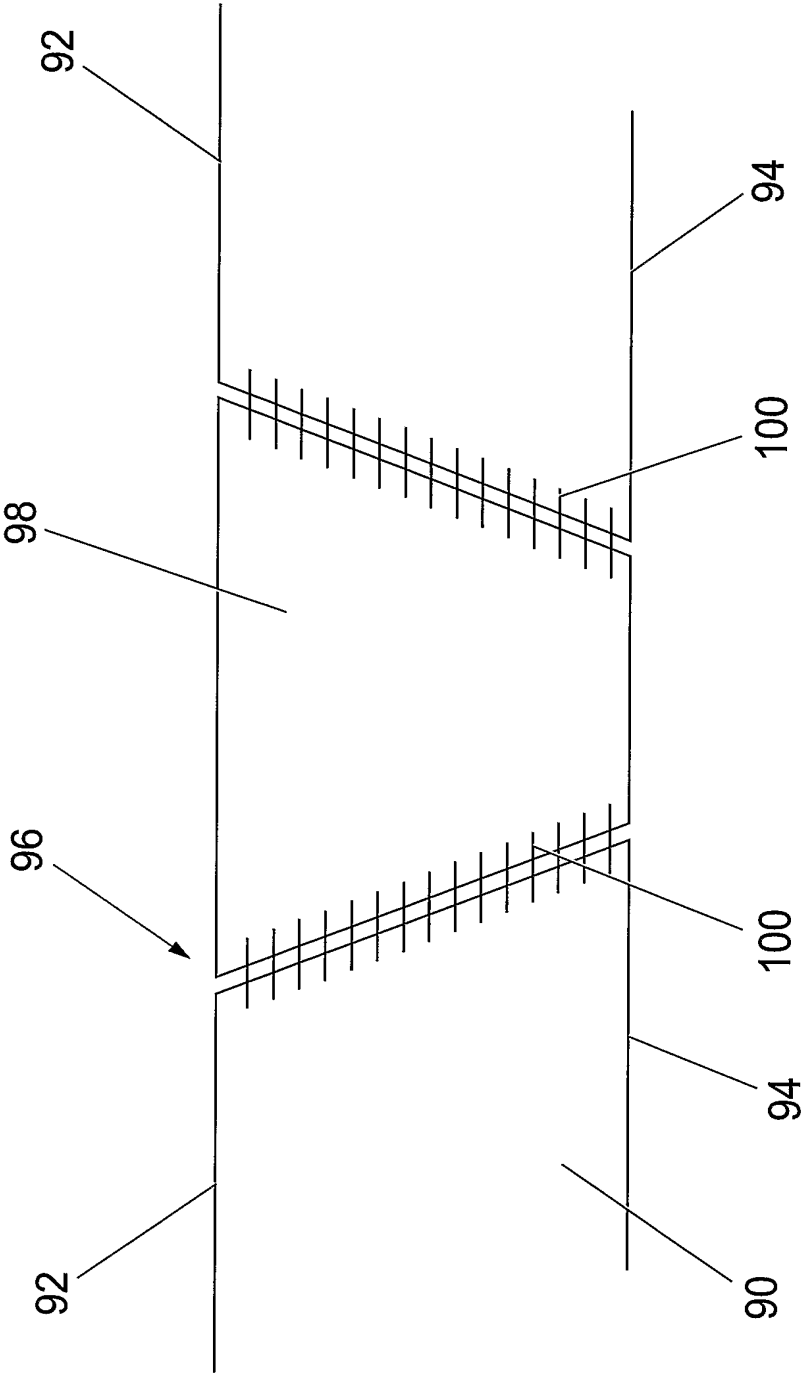


Fig. 17

13 / 13

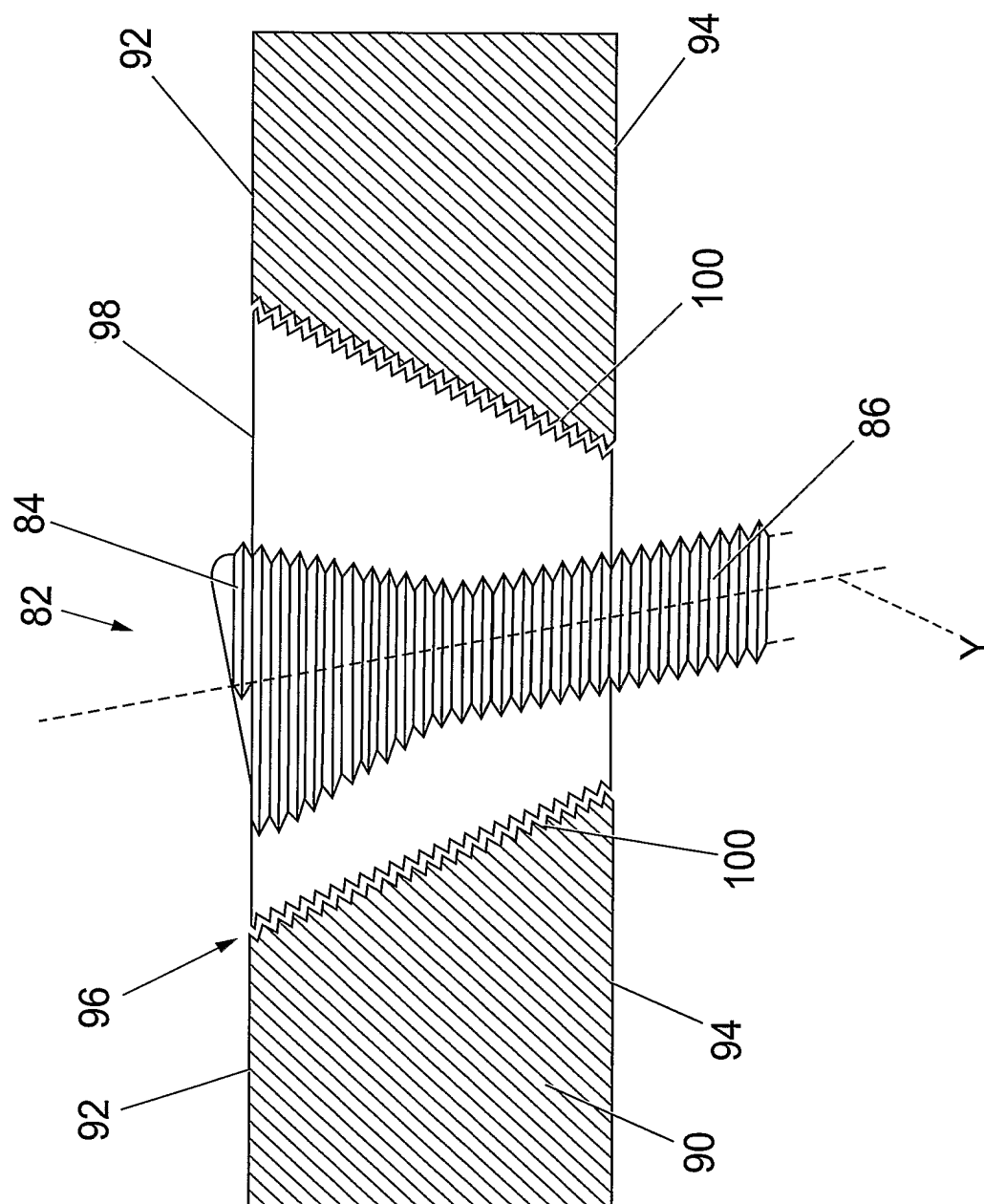


Fig. 18